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**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF NEW YORK**

**STATE OF NEW YORK *ex rel.;***
**and Laurie Khanzadian,**

**Relator/Plaintiff,**

**v.**

**PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLC; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; JOHN DOE, JOHN DOES, OR JOHN DOE CORPORATION, being a fictitious name(s) used to designate a person, persons, partnership, sole proprietorship, corporation or other entity responsible for developing, marketing, and selling prescription opioid drugs,**

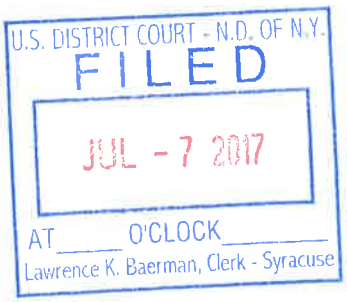
**Defendants.**

**Civil Action**

**No.** 5:17-CV-742 (LEK/ATB)

**COMPLAINT AND JURY DEMAND**

**FILED UNDER SEAL AND *IN CAMERA***
(31 U.S.C. § 3729 *et seq.*)

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## COMPLAINT

1. This is an action is brought under the provisions of the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.* (2009), analogous state laws, and under analogous state fraud laws in New York State.

2. *Qui Tam* Relator/Plaintiff, Laurie Khanzadian, brings this action in the name of the State of New York for false claims that were submitted or caused to be submitted to the State of New York and other federal and state agencies by Defendants.

## INTRODUCTION

3. "Fifty Americans die a day from prescription drug overdoses, and more than 6 million suffer from prescription drug abuse disorders. This is a very real epidemic - and warrants a strong public health response," Andrea Gielen, ScD, Director of the Johns Hopkins Center for Injury Research and Policy.

4. Drug companies should never place their desire for profits above the health and well-being of their customers or the communities where those customers live. Because they know prescribing doctors and other health-care providers rely on drug companies' statements in making treatment decisions, drug companies must tell the truth when marketing their drugs and ensure that their marketing claims are supported by science and medical evidence.

5. Defendants broke these simple rules and helped unleash a healthcare crisis that has had far-reaching financial, social, and deadly consequences in the State of New York. Defendants manufacture, market, and sell prescription opioids (hereinafter "opioids"), including brand-name drugs like Oxycontin and Percocet, and generics like oxycodone and hydrocodone, which are powerful narcotic painkillers. Historically, because these drugs were considered too addictive and debilitating for the treatment of chronic pain, such as back pain, migraines and arthritis (hereinafter, "chronic pain" means non-cancer pain lasting three months or longer), opioids were used only to treat short-term acute pain or for palliative (end-of-life) care.

6. However, by the late 1990s, and continuing today, each Defendant began a marketing scheme designed to persuade doctors and patients that opioids can and should be used

for chronic pain, a far broader group of patients much more likely to become addicted and suffer other adverse effects from the long-term use of opioids. In connection with this scheme, each Defendant spent, and continues to spend, millions of dollars on promotional activities and materials that falsely deny or trivialize the risks of opioids while overstating the benefits of using them for chronic pain. As to the risks, Defendants falsely and misleadingly, and contrary to the language of their drugs' labels: (1) downplayed the serious risk of addiction; (2) promoted the concept of "pseudoaddiction" and thus advocated that the signs of addiction should be treated with more opioids; (3) exaggerated the effectiveness of screening tools in preventing addiction; (4) claimed that opioid dependence and withdrawal are easily managed; (5) denied the risks of higher opioid dosages; and (6) exaggerated the effectiveness of "abuse-deterrent" opioid formulations to prevent abuse and addiction. Conversely, Defendants also falsely touted the benefits of long-term opioid use, including the supposed ability of opioids to improve function and quality of life, even though there was no "good evidence" to support Defendants' claims.

7. Defendants disseminated these common messages to reverse the popular and medical understanding of opioids. They disseminated these messages directly, through their sales representatives, and in speaker groups led by physicians Defendants recruited for their support of Defendants' marketing messages. Borrowing a page from Big Tobacco's playbook, Defendants also worked through third parties they controlled by: (a) funding, assisting, encouraging, and directing doctors, known as "key opinion leaders" ("Paid consultant doctors") and (b) funding, assisting, directing, and encouraging seemingly neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups"). Defendants then worked together with those Paid consultant doctors and Front

Groups to taint the sources that doctors and patients relied on for ostensibly "neutral" guidance, such as treatment guidelines, Continuing Medical Education ("CME") programs, medical conferences and seminars, and scientific articles. Thus, working individually and collectively, and through these Front Groups and Paid consultant doctors, Defendants persuaded doctors and patients that what they had long known - that opioids are addictive drugs, unsafe in most circumstances for long-term use - was untrue, and quite the opposite, that the compassionate treatment of pain *required* opioids.

8. Each Defendant knew that its misrepresentations of the risks and benefits of opioids were not supported by or were directly contrary to the scientific evidence. Indeed, the falsity of each Defendant's misrepresentations has been confirmed by the U.S. Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention ("CDC"), including by the CDC in its *Guideline for Prescribing Opioids for Chronic Pain,* issued in 2016 and approved by the FDA ("2016 CDC Guideline"). Opioid manufacturers, including Defendants Endo Pharmaceuticals, Inc., and Purdue Pharma, L.P., have also entered into settlements agreements with public entities which prohibit these companies from making many of the misrepresentations identified in this Complaint in other jurisdictions. Yet even now, each Defendant continues to misrepresent the risks and benefits of long-term opioid use in New York and continues to fail to correct its past misrepresentations. Defendants' efforts were wildly successful. Opioids are now the most prescribed class of drugs; they generated $11 billion in revenue for drug companies in 2014 alone. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors ... [m]any of [whom] were even taught - incorrectly - that opioids are not addictive when prescribed for legitimate pain."

(Please see Vivek H. Murthy, *Letter from the Surgeon General,* August 2016, attached hereto and incorporated herein by reference as Exhibit "A".) This epidemic, fueled by opioids lawfully prescribed by doctors, has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

9. It is hardly necessary to say - in this Country or this State - that New York is now awash in opioids and engulfed in a public health crisis the likes of which have never been seen before. Between 2005 and 2014, the state documented a 115% increase in heroin treatment admissions in upstate New York and a 116% increase on Long Island. In all, approximately 1.4 million New Yorkers suffer from a substance abuse disorder. (Please see *A Primer on NY's Heroin Epidemic,* New York State Association of Counties, July 2016, attached hereto an incorporated herein by reference as Exhibit "B".)

10. The result of New York's opioid crisis has been catastrophic. Opioids have become the main source of unintentional drug overdose in the state and, due to the vast supply of opioids, the number of annual deaths attributable to unintentional drug overdoses has rapidly increased. During the last five years for which data are available on opioid use, misuse, morbidity, and mortality, both heroin and opioid analgesic-related deaths have increased: 2,175 drug-related deaths were reported in 2013, 40% more than in 2009; heroin was involved in 637 (29%) of drug-related deaths in 2013 vs. 242 (16%) in 2009; opioid analgesic-related deaths increased 30% from 2009 to 2013 (from 735 to 952); naloxone was administered during 11,992 emergency medical services (EMS) calls in 2014 , a 57% increase from the previous year (7,649 in 2013); opioid-related emergency department visits increased 73% from 2010 to 2014; 75,110

opioid-related inpatient hospital admissions were reported in 2014 - an increase of 3% from 2010; and 118,875 (42%) of the 281,800 admissions to NYS certified substance abuse treatment programs in 2014 included "any opioid" as the primary, secondary or tertiary drug problem, up 19% from 2010 (100,004). (Please see *New York State Opioid Poisoning, Overdose and Prevention, 2015 Report to the Governor and NYS Legislature,* New York State Department of Health, attached hereto and incorporated herein by reference as Exhibit "C".

11. In 2009, there were 1,538 reported deaths from unintentional drug poisonings in New York State. Toxicology tests identified heroin in 242 (16%) of these deaths, and opioid analgesics in 735 (48%). In 2013, the latest full year for which data are available, the number of reported drug overdose deaths increased to 2,175, a 41% increase from 2009. The number of heroin-related deaths increased in 2013 to 637, and opioid analgesics related deaths rose to 952, increases of 163% and 30% from 2009, respectively. (Id.)

12. In 2013, an average of two New Yorkers a day died of heroin-related overdoses. More than four times as many men died of one of these overdoses compared to women. Whites died of heroin-related overdoses at a rate of nearly twice that of Blacks (3.95 compared to 2.12), and almost 1.35 times that of Hispanics (2.93). (Id.)

13. The upward trend in heroin-related overdose fatalities among younger New Yorkers is particularly alarming. Half the people who died were under age 35; the numbers rose from 85 deaths in 2009 to 313 in 2013, a 268% increase. Of those 313 deaths, 210 were people aged 25-34 and 103 were aged 15-24. The number of deaths increased among people in all age categories from the previous year. (Id.)

14. The 952 drug-related deaths in 2013 involving prescription opioids (also called "opioid analgesics") represent more than 18 fatalities weekly. The number of New Yorkers aged

45-54, historically the most affected of all age categories, reached a record high of 279 analgesic-associated deaths that year. Nearly twice as many men (612) as women (340) succumbed to these overdoses. Whites died of opioid analgesic-related overdoses at twice the rate of Blacks and Hispanics (6.5 compared to 2.98 and 2.84, respectively). Eight deaths were counted among Asian/Pacific Island New Yorkers in 2013 and none among American Indians/Alaska Natives; however, these racial and ethnic classifications may not reflect the true impact on these populations because of imprecise and incomplete reporting. (Id.)

15. These alarming statistics do not fully illustrate the toll of prescription opioid abuse on patients and their families, as the dramatic increase in opioid prescriptions to treat chronic pain has resulted in a population of addicts who seek drugs from doctors. Efforts by physicians to reverse course for a chronic pain patient with long term dependence on opioids are often thwarted by a secondary criminal market well-stocked by a pipeline of drugs that are diverted to supply these patients.

16. Prescription opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on State agencies that address heroin use and addiction. Individuals who are addicted to prescription opioids often transition to heroin because it is less expensive, readily available, and provides a similar high to the drugs to which they became addicted.

17. New York patients who suffer from chronic pain deserve both appropriate care and the ability to make decisions based on accurate and complete information about treatment risks and benefits. Defendants' deceptive marketing campaign has and continues to deprive New York patients and their doctors of the ability to make informed medical decisions and, instead, caused important, sometimes life-or-death

decisions to be made based not on science, but on hype. Defendants deprived patients, their doctors, and health care payors of the chance to exercise informed judgment and subjected them to enormous costs and suffering.

18. Defendants' conduct has also exacted, and foreseeably so, a financial burden on the State of New York. The New York State's Department of Health, its counties' Departments of Social Services and Medicaid, as well as New York's Workers' Compensation have spent hundreds of millions of dollars on opioid prescriptions for chronic pain. In addition, these agencies have spent tens of millions more on costs directly attributable to the flood of opioids Defendants unleashed on the State, including costs for addiction treatment and the treatment of babies born addicted to opioids.

19. To redress these violations of law, and the Defendants' reckless and wanton behavior and total disregard for the rights and well-being of the citizens of the United States, the State of New York, the Relator/Plaintiff Laurie Khanzadian, seeks damages for the amounts the State of New York has paid for excessive opioid prescriptions and in connection with the results of those prescriptions (*e.g.,* addiction treatment costs). The Relator/Plaintiff also seeks punitive damages, treble damages, and attorneys' fees and costs, in addition to granting any other equitable relief authorized by law.

## PARTIES

20. *Qui Tam* Relator/Plaintiff Laurie Khanzadian lives and resides in the City of Syracuse, County of Onondaga and State of New York, and is a citizen of the United States. The *Qui Tam* Relator/Plaintiff tragically lost her 79-year-old mother Jeanne L. Armstrong on April 8, 2015 after the vehicle she was driving was struck head-on by David Yarinich ("Yarinich"). Yarinich

admitted, during a later criminal court appearance, to being high on heroin at the time he crossed the center line of Kasson Road, in the Town of Onondaga, County of Onondaga, State of New York, and caused the collision with Jeanne L. Armstrong's vehicle, causing her death. Yarinich had used a bag of heroin less than two hours before the crash; a hypodermic needle was found in his car. Yarinich's addiction to heroin developed out of an addiction to opioid drugs, which were initially lawfully prescribed by his medical care providers and were developed, marketed, and sold to him and other patients residing in New York State through false, misleading and deceptive practices that such drugs were a safe and effective way to treat pain and/or chronic pain, with absolutely no concern for the toll that prescription opioid abuse would have on Yarinich and other patients in New York State and their families and their communities.

21. PURDUE PHARMA, L.P. is a limited partnership organized under the laws of Delaware. PURDUE PHARMA, INC. is a New York corporation with its principal place of business in Stamford, Connecticut, and THE PURDUE FREDERICK COMPANY is a Delaware corporation with its principal place of business in Stamford, Connecticut (collectively, hereinafter "Purdue"). Upon information and belief, the Pursue Defendants are authorized to do business in the State of New York.

22. Purdue is in the business of manufacturing, promoting, selling, and distributing opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the U.S. and in the State of New York. The drug OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

23. CEPHALON, INC. is a Delaware corporation with its principal place of business

in Frazer, Pennsylvania. TEVA PHARMACEUTICAL INDUSTRIES, LTD. (hereinafter, "Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva, Ltd., acquired Cephalon, Inc. TEVA PHARMACEUTICALS USA, INC. (hereinafter, "Teva USA") is a wholly- owned subsidiary of Teva, Ltd,. and is a Delaware corporation with its principal place of business in Pennsylvania. Teva USA acquired Cephalon in October 2011. Upon information and belief, the Cephalon and Teva Defendants are authorized to do business in the State of New York.

24. Cephalon, Inc., manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the U.S. and in the State of New York. Actiq and Fentora have been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain." Breakthrough pain is a short-term flare of moderate-to-severe pain in patients with otherwise stable persistent pain. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay $425 million.

25. Teva Ltd., Teva USA, and Cephalon, Inc., work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its acquisition of Cephalon in October of 2011. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is distributed with Cephalon opioids marketed and sold in New York, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report

adverse events. Teva Ltd. has directed Cephalon, Inc., to disclose that it is a wholly-owned subsidiary of Teva Ltd. on prescription savings cards distributed in New York, indicating Teva Ltd. would be responsible for covering certain co-pay costs. All of Cephalon's promotional websites, including those for Actiq and Fentora, prominently display Teva Ltd.'s logo. Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 - the year immediately following the Cephalon acquisition - attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales." Through interrelated operations like these, Teva Ltd. operates in New York and the rest of the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Upon information and belief, Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder. (hereinafter, Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. are referred to as "Cephalon.")

26. JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of JOHNSON & JOHNSON (hereinafter, "J&J"), a New Jersey corporation, with its principal place of business in New Brunswick, New Jersey. ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. JANSSEN PHARMACEUTICA, INC., now known as JANSSEN PHARMACEUTICALS, INC., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock, and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit. (Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., and J&J are hereinafter collectively referred to as "Janssen."). Upon information and belief, the Janssen Defendants are authorized to do business in the State of New York.

27. Janssen manufactures, promotes, sells, and distributes drugs in the U.S. and New York, including the opioid Duragesic. Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

28. ENDO HEALTH SOLUTIONS, INC., is a Delaware corporation with its principal place of business in Malvem, Pennsylvania. ENDO PHARMACEUTICALS, INC., is a wholly- owned subsidiary of ENDO HEALTH SOLUTIONS, INC., and is a Delaware corporation with its principal place of business in Malvem, Pennsylvania. (Endo Health Solutions, Inc., and Endo Pharmaceuticals, Inc., are hereinafter collectively referred to as "Endo."). Upon information and belief, the Endo Defendants are authorized to do business in the state of New York.

29. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the U.S. and New York. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013, and it accounted for 10% of Endo's total revenue in

2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the U.S. and New York, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

30. ALLERGAN, PLC, is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. ACTAVIS, PLC, acquired ALLERGAN, PLC, in March of 2015, and the combined company changed its name to ALLERGAN, PLC, in June of 2015. Before that, WATSON PHARMACEUTICALS, INC., acquired ACTAVIS, INC., in October 2012, and the combined company changed its name to ACTAVIS, INC., as of January 2013 and then ACTAVIS, PLC, in October 2013. WATSON LABORATORIES, INC., is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). ACTAVIS PHARMA, INC. (f/k/a Actavis, Inc.), is a Delaware corporation with its principal place of business in New Jersey and was formerly known as WATSON PHARMA, INC. ACTAVIS, LLC, is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Each of these defendants is owned by ALLERGAN, PLC, which uses them to market and sell its drugs in the United States. Upon information and belief, ALLERGAN, PLC, exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products ultimately inure to its benefit. (Allergan, PLC, Actavis, PLC, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. are hereinafter collectively referred to as "Actavis."). Upon information and belief, the Actavis Defendants are authorized to do business in the State of New York.

31. Actavis manufactures, promotes, sells, and distributes opioids, including the

branded drugs Kadian and Norco, a generic version of Radian, and generic versions of Duragesic and Opana, in the U.S. and New York. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008, and began marketing Kadian in 2009.

32. Relator/Plaintiff lacks information sufficient to specifically identify the true names or capacities, whether individual, corporate or otherwise, of the Defendants sued herein under the fictitious names of JOHN DOE, JOHN DOES, OR JOHN DOE CORPORATION, being a fictitious name(s) used to designate a person, persons, partnership, sole proprietorship, corporation or other entity, who is responsible in some manner for the events and occurrences alleged in this Complaint and is liable for the relief sought herein. The Relator/Plaintiff will amend this Complaint to show their true names and capacities if and when they are ascertained.

## JURISDICTION AND VENUE

33. This action arises under 31 U.S.C. § 3729, *et seq.* Therefore, this is a case or controversy arising under the laws of the United States and the State of New York. Hence, this Court also has subject matter jurisdiction under 28 U.S.C. § 1331 (2008).

34. This action also includes claims under the New York False Claims Act and for fraud under New York State law. The Court has supplemental jurisdiction over these state claims under 28 U.S.C. §1367.

35. This action may be brought in this judicial district under 31 U.S.C. § 3732(a) (2009) because, *inter alia*, the Relator/Plaintiff resides in this district and the Defendants transacted business in this judicial district.

## FACTUAL ALLEGATIONS

36. Relator/Plaintiff repeats, re-alleges and incorporates by reference all allegations set forth above as if fully set forth below.

37. Prior to the 1990s, generally accepted standards of medical practice dictated that opioids should only be used short-term for acute pain, surgical pain during recovery, or for cancer or palliative (end-of-life) care. Due to the lack of evidence that opioids improved patients' ability to overcome pain and function, coupled with evidence of greater pain complaints as patients developed tolerance to opioids over time and the serious risk of addiction and other side effects, the use of opioids for chronic pain was discouraged or prohibited. As a result, doctors generally did not prescribe opioids for chronic pain.

38. For profit sake, each Defendant took advantage of the lucrative market for chronic pain patients and developed a well-funded marketing scheme based on deceptive practices. Each Defendant used both direct marketing and unbranded advertising disseminated by so called independent third parties to spread false and deceptive statements about the risks and benefits of long-term opioid use, which statements only benefited each Defendant but also other Defendants and opioid manufacturers. These statements, however, were unsupported by and contrary to the scientific evidence and to pronouncements by and guidance from the FDA and CDC based on that evidence. They also targeted susceptible and vulnerable patient populations.

39. Defendants spread their false and deceptive statements by marketing their branded opioids directly to physicians and their patients in the State of New York. Defendants also deployed seemingly unbiased and independent third parties that they controlled to spread their false and deceptive statements about the risks and benefits of opioids for the treatment of chronic pain throughout the State of New York.

40. Defendants' direct marketing of opioids includes conducting and continuing to conduct advertising campaigns that push the supposed benefits of their branded drugs. In 2011, Defendants spent more than $14 million on medical journal advertising of opioids, which is

nearly triple of what they spent in 2001. This amount included $8.3 million by Purdue, $4.9 million by Janssen, and $1.1 million by Endo. A number of Defendants' branded ads deceptively portrayed the benefits of opioids for chronic pain; and have expressly and impliedly misled and misrepresented that their drug would provide long-term pain-relief and functional improvement.

41. Defendants' direct marketing of opioids includes promoting and continuing to promote the use of opioids for chronic pain through sales representatives, also known as "detailers" who visit individual doctors and medical staff in their offices or conduct small-group speaker programs. To date, Defendants have not corrected this misinformation. Instead, each Defendant devoted and continues to devote massive resources to direct sales contacts with doctors. In 2014 alone, Defendants spent $168 million on detailing brand opioids to physicians, which is twice as much as they spent on this practice in 2000. The amount includes $108 million spent by Purdue, $34 million by Jansen, $13 million by Cephalon, $10 million by Endo and $2 million by Actavis. Defendants' detailers have been reprimanded for their deceptive promotions, including, by organizations such as the FDA.

42. Defendants also spoke through a small circle of doctors (hereinafter "paid consultant doctors") who, upon information and belief, were selected, funded, and elevated by Defendants because their public positions supported the use of opioids to treat chronic pain. Defendants used many paid consultant doctors, including many of the same ones, the two most prominent are set forth below.

43. Dr. Russell Portenoy, former Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York. Dr. Portenoy received research support, consulting fees, and honoraria from Cephalon, Endo, Janssen, and Purdue (among others), and was a paid consultant to Cephalon and Purdue. Dr. Portenoy was

instrumental in opening the door for the regular use of opioids to treat chronic pain. He served on the American Pain Society ("APS") / American Academy of Pain Medicine ("AAPM") Guidelines Committees, which endorsed the use of opioids to treat chronic pain, first in 1997 and again in 2009. He was also a member of the board of the American Pain Foundation ("APF"), an advocacy organization almost entirely funded by Defendants. Dr. Portenoy also made frequent media appearances promoting opioids and spreading misrepresentations. He appeared on *Good Morning America* in 2010 to discuss the use of opioids long-term to treat chronic pain. On this widely-watched program, broadcast in New York and across the country, Dr. Portenoy claimed: "Addiction, when treating pain, is distinctly uncommon. If a person does not have a history, a personal history, of substance abuse, and does not have a history in the family of substance abuse, and does not have a very major psychiatric disorder, most doctors can feel very assured that that person is not going to become addicted." To his credit, Dr. Portenoy later admitted that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true." These lectures falsely claimed that fewer than 1% of patients would become addicted to opioids. According to Dr. Portenoy, because the primary goal was to "destigmatize" opioids, he and other doctors promoting them overstated their benefits and glossed over their risks. Dr. Portenoy also conceded that "[d]ata about the effectiveness of opioids does not exist." Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, ... I guess I did." (Please see Thomas Catan & Evan Perez, *A Pain-Drug Champion Has Second Thoughts,* WALL ST. J., Dec 17, 2012.)

44. Dr. Lynn Webster, was the co-founder and Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster

was President in 2013 and is a current board member of AAPM, a front group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine,* the same journal that published Endo special adve1tising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly $2 million from Cephalon). Dr. Webster was under investigation for overprescribing by the U.S. Department of Justice's Drug Enforcement Agency, which raided his clinic in 2010. Although the investigation was closed without charges in 2014, more than 20 of Dr. Webster's former patients at the Lifetree Clinic have died of opioid overdoses. Ironically, Dr. Webster created and promoted the Opioid Risk Tool, a five question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk.* Dr. Webster recommended use of risk screening tools, urine testing, and patient agreements as a way to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach New York doctors. Dr. Webster also was a leading proponent of the concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated pain. In Dr. Webster's description, the only way to differentiate the two was to *increase* a patient's dose

of opioids. As he and his co-author wrote in a book entitled *Avoiding Opioid Abuse While Managing Pain* (2007), a book that is still available online, when faced with signs of aberrant behavior, increasing the dose "in most cases ... should be the clinician's first response." Endo distributed this book to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication. (Please see John Fauber & Ellen Gabler, *Networking Fuels Painkiller Boom,* MILWAUKEE WISC. J. SENTINEL (Feb. 19, 2012.)

45. Defendants identified and paid these doctors to serve on their speakers' bureaus and advisory boards, and to attend programs with speakers and meals paid for by Defendants. These speaker programs provided incentives for doctors to prescribe a particular opioid, recognition and compensation for the doctors selected as speakers, and an opportunity to promote the drug through the speaker to his or her peers. These paid speakers gave the false impression that they were providing unbiased and medically accurate presentations when they were, in fact, presenting a script prepared by Defendants. Upon information and belief, these presentations conveyed biased, misleading information, omitted material information, and failed to correct Defendants' prior misrepresentations about the risks and benefits of opioids.

46. Defendants employed the same marketing plans and strategies and deployed the same messages in New York as they did nationwide. Across the pharmaceutical industry, "core message" development is funded and overseen on a national basis by corporate headquarters. This comprehensive approach ensures that Defendants' messages are accurately and consistently delivered across marketing channels, which include detailing visits, speaker events, and advertising, and in each sales territory. Defendants consider this high level of coordination and uniformity crucial to successfully marketing their drugs.

47. Defendants ensure marketing consistency nationwide through national and regional sales representative training; national training of local medical liaisons, the company employees who respond to physician inquiries; centralized speaker training; single sets of visual aids, speaker slide decks, and sales training materials; and nationally coordinated advertising. Defendants' sales representatives and physician speakers were required to stick to prescribed talking points, sales messages, and slide decks, and supervisors rode along with them periodically to both check on their performance and compliance.3721

48. Defendants also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of Defendants, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that favored chronic opioid therapy. Defendants exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants made sure that the Front Groups would generate only the messages Defendants wanted to distribute. The Front Groups also assisted Defendants by responding to negative articles, by advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific evidence, and by conducting outreach to vulnerable patient populations targeted by Defendants.

49. These Front Groups depended on Defendants for funding and, in some cases, for survival. Defendants also exercised control over programs and materials created by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, Defendants made sure that the Front Groups would generate only the messages Defendants wanted to distribute. Despite this, the Front Groups held themselves out as

independent and serving the needs of their members, whether it was the patients suffering from pain or doctors treating those patients.

50. Defendants Cephalon, Endo, Janssen, and Purdue utilized many Front Groups, including many of the same ones. Several of the most prominent are described below, but there are many others, including the American Pain Society ("APS"), American Geriatrics Society ("AGS"), the Federation of State Medical Boards ("FSMB"), American Chronic Pain Association ("ACPA"), American Society of Pain Education ("ASPE"), National Pain Foundation ("NPF") and Pain & Policy Studies Group ("PPSG").

51. These Front Groups, among others utilized by Defendants, advertised and promoted, and continue to advertise and promote, opioid use generally, but did not name a specific opioid. This advertising was ostensibly created and disseminated by independent third parties, these Front Groups. But by funding, directing, reviewing, editing, and distributing this unbranded advertising, Defendants controlled the deceptive messages disseminated by these third parties and acted in concert with them to falsely and misleadingly promote opioids for the treatment of chronic pain. Much as Defendants controlled the distribution of their "core messages" via their own detailers and speaker programs, Defendants similarly controlled the distribution of these messages in scientific publications, treatment guidelines, CMEs, and medical conferences and seminars. To this end, Defendants used third-party public relations firms to help control those messages when they originated from third-parties.

52. Defendants also marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and typically is not reviewed by the FDA. Defendants also used third-party, unbranded advertising to give the false

appearance that the deceptive messages came from an independent and objective source. Like the tobacco companies, Defendants used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long- term opioid use for chronic pain.

53. Due to the close relationship between the Front Groups and the Defendants, the clear lack of independence of the Front Groups - in their finances, management, and mission - and their willingness to allow Defendants to control their activities and messages, support an inference that each Defendant that worked with the Front Groups was able to exercise editorial control over each group's publications.

54. The warnings on Defendants' own FDA-approved drug labels caution that opioids "expose users to risks of addiction, abuse and misuse, which can lead to overdose and death," that the drugs contain "a substance with a high potential for abuse," and that addiction "can occur in patients appropriately prescribed" opioids. Defendants' deceptive unbranded marketing contradicted what they said in their branded materials reviewed by the FDA. For example, Endo's unbranded advertising contradicted its concurrent, branded advertising for Opana ER:

| **Pain: Opioid Therapy** | **Opana ER Advertisement** |
|---|---|
| **(Unbranded)** | **(Branded)** |
| "People who take opioids **as prescribed usually do not become addicted."** | "All patients treated with opioids require careful monitoring for signs of abuse and addiction, since **use of opioid analgesic products carries the risk of addiction even under appropriate medical use."** |

55. To convince physicians and patients in New York that opioids can and should be used to treat chronic pain, Defendants used deceptive practices to pursue them that long-term opioid use is both safe and helpful. Knowing that they could do so only by deceiving those doctors and patients about the risks and benefits of long-term opioid use, Defendants made false claims that were not supported by or were contrary to the scientific evidence. Even though pronouncements by and guidance from the FDA and the CDC based on that evidence confirm that their claims were false and deceptive, Defendants have not corrected them, nor have they instructed their paid consultant doctors or Front Groups to correct them, and each continues to spread these deceptions today.

56. To convince physicians and patients that opioids are safe, Defendants deceptively trivialized and failed to disclose the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been conclusively debunked by the FDA and CDC. These misrepresentations reinforced each other and created the dangerously misleading impression that starting patients on opioids was low- risk because most patients would not become addicted; and those who were at greatest risk of addiction could be readily identified and managed; and patients who displayed signs of addiction probably were not addicted and, in any event, could easily be weaned from the drugs; and the use of higher opioid doses, which many patients need to sustain pain relief as they develop tolerance to the drugs, do not pose special risks; and abuse-deterrent opioids both prevent abuse and overdose and are inherently less addictive. Defendants have not only failed to correct these misrepresentations, they continue to mislead and make these false representations today.

57. Defendants falsely claimed that the risk of addiction is low and that addiction is unlikely to develop when opioids are prescribed, as opposed to obtained illicitly; and failed to

disclose the greater risk of addiction with prolonged use of opioids. Some illustrative examples of these false and deceptive claims are hereinafter set forth, as follows: (1) Actavis' predecessor caused a patient education brochure to be distributed in 2007 that claimed opioid addiction is possible, but "less likely if you have never had an addiction problem." Upon information and belief, based on Actavis' acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use this brochure in 2009 and beyond; (2) Cephalon and Purdue sponsored APF's Treatment Options: A Guide for People Living with Pain (2007), which instructed that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft. This publication is still available online and is attached hereto and incorporated herein by reference as Exhibit "D"; (3) Endo sponsored a website, Painknowledge.com, which claimed in 2009 that "[people who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them."; (4) Endo distributed a pamphlet with the Endo logo entitled Living with Someone with Chronic Pain, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem." A similar statement appeared on the Endo website www.opana.com; (5) Janssen reviewed, edited, approved, and distributed a patient education guide entitled Finding Relief: Pain Management for Older Adults (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."; (6) Janssen currently runs a website, Prescriberesponsibly.com (last updated July 2,2015), which claims that concerns about opioid addiction are "overestimated."; (7) Purdue sponsored APF's A Policymaker's Guide to

Understanding Pain & Its Management - which claims that less than 1% of children prescribed opioids will become addicted and that pain is undertreated due to "misconceptions about opioid addiction." This publication is still available online and is attached hereto and incorporated by reference as Exhibit "E"; (8) Detailers for Purdue, Endo, Janssen, and Cephalon in the State of New York minimized or omitted any discussion with doctors of the risk of addiction; misrepresented the potential for abuse of opioids with purportedly abuse- deterrent formulations; and routinely did not correct the misrepresentations noted above.

58. All of these claims are contrary to longstanding scientific evidence, as the FDA and CDC have conclusively declared. As noted in the 2016 CDC *Guideline for Prescribing Opioids for Chronic Pain – United State 2016*, endorsed by the FDA, there is "extensive evidence" of the "possible harms of opioids (including opioid use disorder [an alternative term for opioid addiction])." The *Guideline* points out that "[o]pioid pain medication use presents serious risks, including ... opioid use disorder" and that "continuing opioid therapy for 3 months substantially increases risk for opioid use disorder." A copy of The *Guideline* is attached hereto and incorporated herein by reference and marked Exhibit "F".

59. The FDA further exposed the falsity of Defendants' claims about the low risk of addiction when it announced changes to the labels for ER/LA opioids in 2013 and for intermediate release ("IR") opioids in 2016. In its announcements, the FDA found that "most opioid drugs have 'high potential for abuse'" and that opioids "are associated with a substantial risk of misuse, abuse, NOWS [neonatal opioid withdrawal syndrome], addiction, overdose, and death." According to the FDA, because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for

whom alternative treatment options" like non-opioid drugs have failed. The FDA further acknowledged that the risk is not limited to patients who seek drugs illicitly; addiction "can occur in patients appropriately prescribed [opioids]."

60. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers meeting the clinical criteria for an opioid use disorder." Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that ... opioids generally are non-addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free to make those statements in other states.

61. Defendants falsely instructed doctors and patients that the signs of addiction are actually signs of under-treated pain and should be treated by prescribing more opioids. Defendants called this phenomenon "pseudoaddiction"- a term coined by Dr. David Haddox, who went to work for Purdue, and popularized by Dr. Russell Portenoy, a consultant doctor for Cephalon, Endo, Janssen, and Purdue - and falsely claimed that pseudoaddiction is substantiated by scientific evidence. Some illustrative examples of these deceptive claims are: a) Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding, are all signs of pseudoaddiction, rather than true addiction.

Responsible Opioid Prescribing remains for sale online. The 2012 edition, which also remains available online, continues to teach that pseudoaddiction is real; b) Janssen sponsored, funded, and edited the *Let's Talk Pain* website, which in 2009 stated: "pseudoaddiction ... refers to patient behaviors that may occur when pain is under-treated ....Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management;" c) Endo sponsored a National Initiative on Pain Control (NIPC) CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia,* which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo substantially controlled NIPC by funding NIPC projects; developing, specifying, and reviewing content; and distributing NIPC materials; d) Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse,* which described pseudoaddiction as a concept that "emerged in the literature" to describe the inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated; and e) Purdue sponsored a CME program entitled *Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse.* In a role play, a chronic pain patient with a history of drug abuse tells his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high-dose, long-acting opioid.

62. The 2016 CDC Guideline (attached hereto as Exhibit "F") rejects the concept of pseudoaddiction. The Guideline nowhere recommends that opioid dosages be increased if

a patient is not experiencing pain relief. To the contrary, the Guideline explains that "[p]atients who do not experience clinically meaningful pain relief early in treatment ... are unlikely to experience pain relief with longer- term use," and that physicians should "reassess[] pain and function within 1 month" in order to decide whether to "minimize risks of long-term opioid use by discontinuing opioids" because the patient is "not receiving a clear benefit."

63. Even one of the Defendants has effectively repudiated the concept of pseudoaddiction. In finding that "[t]he pseudoaddiction concept has never been empirically validated and in fact has been abandoned by some of its proponents," the State of New York, in its 2016 settlement with Endo, rep1ied that "Endo's Vice President for Pharmacovigilance and Risk Management testified that he was not aware of any research validating the 'pseudoaddiction' concept" and acknowledged the difficulty in distinguishing "between addiction and 'pseudoaddiction."' Consistent with this, Endo agreed not to "use the te1m 'pseudoaddiction' in any training or marketing" in New York. Endo, however, remains free to do so in other states.

64. Defendants falsely instructed doctors and patients that addiction risk screening tools, patient contracts, urine drug screens, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. These misrepresentations were especially insidious because Defendants aimed them at general practitioners and family doctors who lack the time and expertise to closely manage higher-risk patients on opioids. Defendants' misrepresentations made these doctors feel more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain. Some illustrative examples of these deceptive claims are: a)

Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids,* emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts; b) Purdue sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk,* which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose death;" and c) As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients - and not opioids - are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

65. The 2016 CDC Guideline confirms the falsity of these misrepresentations. The Guideline notes that there are no studies assessing the effectiveness of risk mitigation strategies - such as screening tools, patient contracts, urine drug testing, or pill counts widely believed by doctors to detect and deter abuse - "for improving outcomes related to overdose, addiction, abuse, or misuse." As a result, the Guideline recognizes that available risk screening tools "show insufficient accuracy for classification of patients as at low or high risk for [opioid] abuse or misuse" and counsels that doctors "should not overestimate the ability of these tools to rule out risks from long-term opioid therapy." (Please see Exhibit "F".)

66. To underplay the risk and impact of addiction and make doctors feel more comfortable starting patients on opioids, Defendants falsely claimed that opioid dependence

can easily be addressed by tapering and that opioid withdrawal is not a problem, and failed to disclose the increased difficulty of stopping opioids after long-term use.

67. Defendants deceptively minimized the significant symptoms of opioid withdrawal-which, as explained in the 2016 CDC Guideline, include drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating, tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant women, and the unmasking of anxiety, depression, and addiction- and grossly understated the difficulty oftapering, particularly after long-term opioid use. Yet the 2016 CDC Guideline recognizes that the duration of opioid use and the dosage of opioids prescribed should be "limit[ed]" to "minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms," because "physical dependence on opioids is an expected physiologic response in patients exposed to opioids for more than a few days." The Guideline further states that "tapering opioids can be especially challenging after years on high dosages because of physical and psychological dependence" and highlights the difficulties, including the need to carefully identify "a taper slow enough to minimize symptoms and signs of opioid withdrawal" and to pause and restart tapers depending on the patient's response. The CDC also acknowledges the lack of any "high-quality studies comparing the effectiveness of different tapering protocols for use when opioid dosage is reduced or opioids are discontinued."

68. Defendants falsely claimed that doctors and patients could increase opioid dosages indefinitely without added risk and failed to disclose the greater risks to patients at higher dosages. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation,

doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. Some illustrative examples are: a) Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Upon information and belief, based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis continued to use these materials in 2009 and beyond; b) Cephalon and Purdue sponsored *APF's Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have "no ceiling dose" and are therefore the most appropriate treatment for severe pain. This guide is still available for sale online; c) Endo sponsored a website, painknowledge.com, which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain;" d) Endo distributed a pamphlet edited by a consultant doctor entitled *Understanding Your Pain: Taking Oral Opioid Analgesics,* which was available during the time period of this Complaint on Endo's website. In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased...You won't 'run out' of pain relief;" e) Janssen sponsored a patient education guide entitled *Finding Relief Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages; f) Purdue's In the Face of Pain website promotes the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will; g) Purdue sponsored APF's *A Policymaker's Guide*

*to Understanding Pain & Its Management,* which taught that dosage escalations are "sometimes necessary," even unlimited ones, but did not disclose the risks from high opioid dosages. This publication is still available online; h) Purdue sponsored a CME entitled *Overview of Management Options* that is still available for CME credit. The CME was edited by a consultant doctor and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages; and i) Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, the "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.

69. As the CDC explains in its 2016 Guideline, the "[b]enefits of high-dose opioids for chronic pain are not established" while the "risks for serious harms related to opioid therapy increase at higher opioid dosage." More specifically, the CDC explains that "there is now an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that "there is an increased risk for opioid use disorder, respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosages" above 90 morphine milligram equivalents *per* day. The 2016 CDC Guideline reinforces earlier findings announced by the FDA. In 2013, the FDA acknowledged "that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events." For example, the FDA noted that studies "appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality."

70. Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can curb addiction and

abuse. Indeed, in a 2014 survey of 1,000 primary care physicians, nearly half reported that they believed abuse-deterrent formulations are inherently less addictive. More specifically, Defendants have made misleading claims about the ability of their so-called abuse-deterrent opioid formulations to deter abuse. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that there was no evidence Endo's design "would provide a reduction in oral, intranasal or intravenous abuse." Moreover, Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed.

71. In a 2016 settlement with the State of New York, Endo agreed not to make statements in New York that Opana ER was "designed to be, or is crush resistant." The State found those statements false and deceptive because there was no difference in the ability to extract the narcotic from Opana ER. Similarly, the 2016 CDC Guideline states that "no studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies - even when they work- "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by nonoral routes."

72. These numerous, longstanding misrepresentations of the risks of long-term opioid use spread by Defendants successfully convinced doctors and patients to discount those risks.

73. To convince doctors and patients that opioids should be used to treat chronic pain, Defendants also had to persuade them that there was a significant upside to long-term opioid use. However, the 2016 CDC Guideline makes clear, there is "insufficient evidence

to determine the long-term benefits of opioid therapy for chronic pain." In fact, the CDC found that "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least one year later (with most placebo-controlled randomized trials [equal to or greater than] 6 weeks in duration)" and that other treatments were more or equally beneficial and less harmful than long-term opioid use. The FDA, too, has recognized the lack of evidence to support long-term opioid use. In 2013, the FDA stated that it was "not aware of adequate and well-controlled studies of opioids use longer than 12 weeks." Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence. Not only have Defendants failed to correct these false and deceptive claims, they continue to make them today.

74. Defendants falsely claimed that long-term opioid use improved patients' function and quality of life. Some illustrative examples are: a) Actavis distributed an advertisement that claimed that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives; b) Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects; c) Janssen sponsored and edited a patient education guide entitled *Finding Relief Pain Management for Older Adults* (2009) - which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs; d) Purdue ran a series of advertisements for OxyContin in 2012 in medical

journals entitled "Pain vignettes," which were case studies featuring patients with pain conditions persisting over several months and recommending OxyContin for them. The ads implied that OxyContin improves patients' function; e) *Responsible Opioid Prescribing* (2007), sponsored and distributed by Cephalon, Endo and Purdue, taught that relief of pain by opioids, by itself, improved patients' function. The book remains for sale online; f) Cephalon and Purdue sponsored APF's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." The guide was available online until APF shut its doors in 2012; g) Endo's NIPC website *painknowledge.com* claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC's intent to make misleading claims about function, and Endo closely tracked visits to the site; h) Endo was the sole sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient,* which claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning." The CME was disseminated via webcast; i) Janssen sponsored, funded, and edited a website, *Let's Talk Pain,* in 2009, which featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function." This video is still available today on YouTube; j) Purdue sponsored the development and distribution of APF's *A Policymaker's Guide to Understanding Pain & Its Management,* which claimed that "multiple clinical studies" have shown that opioids are effective in improving daily function,

psychological health, and health- related quality of life for chronic pain patients." The Policymaker's Guide was originally published in 2011 and is still available online today; and k) Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

75. These claims find no support in the scientific literature. The FDA and other federal agencies have made this clear for years. Most recently, the 2016 CDC Guideline approved by the FDA concluded that "there is no good evidence that opioids improve pain or function with long-term use, and ... complete relief of pain is unlikely."

76. The CDC also noted that the 1isks of addiction and death "can cause distress and inability to fulfill major role obligations." As a matter of common sense (and medical evidence), drugs that can kill patients or commit them to a life of addiction or recovery do not improve their function and quality of life.

77. The 2016 CDC Guideline was not the first time a federal agency repudiated Defendants' claim that opioids improved function and quality of life. In 2010, the FDA warned Actavis, in response to its advertising described in paragraph 40, that "[w]e are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience ... results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." (Please see Actavis Elizabeth, LLC, promotional material "... *When you can prescribe the benefits of Kadian capsules?*, attached hereto and incorporated herein by reference as Exhibit "G"; and Warning Letter from Thomas Abrams, Dir. FDA Div. of Mktg, Adver., &

Commc'ns, to Doug Boothe, CEO, Actavis Elizabeth, LLC (Feb. 18, 2010, attached hereto and incorporated herein by reference as Exhibit "H".)

78. Defendants also falsely and misleadingly emphasized or exaggerated the risks of competing products like NSAIDs, so that doctors and patients would look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by Defendants contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for ER/LA opioids in 2013 and IR opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options" like non-opioid drugs "are inadequate." And the 2016 CDC Guideline states that NSAIDs, not opioids, should be the fast-line treatment for chronic pain, particularly arthritis and lower back pain.

79. In addition, Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours - a fact that Purdue has known at all times relevant to this action. According to Purdue's own research, OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial number" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more

OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence.

80. Among Defendants' other unlawful, unfair and fraudulent misconduct, Cephalon deceptively marketed its opioids Actiq and Fentora for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid- tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based IR opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse - which are greatest in non-cancer patients. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be used for any other conditions, such as migraines, post-operative pain, or pain due to injury.

81. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, or safe. As part of this campaign, Cephalon used CMEs, speaker programs, paid consultant doctors, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain. For example: a) Cephalon paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain,* published in a supplement of *Pain Medicine News* in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or noncancer-related has limited

utility" and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online; b) Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain; and c) In December 2011, Cephalon widely disseminated a journal supplement entitled *"Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTJQ)"* to *Anesthesiology News, Clinical Oncology News,* and *Pain Medicine News* - three publications that are sent to thousands of anesthesiologists and other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" - and not just cancer pain.

82. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

83. Purdue also unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Rather than report these doctors to state medical boards or law enforcement authorities (as Purdue is legally obligated to do) or cease marketing to them, Purdue used the list to demonstrate the high rate of diversion of OxyContin - the same OxyContin that Purdue had promoted as less addictive - in order to persuade the FDA to bar the manufacture and sale of generic copies of the drug because the drug was too likely to be abused. In an interview with the *Los Angeles Times,* Purdue's senior compliance officer acknowledged that in five years of investigating suspicious

pharmacies, Purdue failed to take action - even where Purdue employees personally witnessed the diversion of its drugs. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report until years after law enforcement shut down a Los Angeles clinic that prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described internally as "an organized drug ring." In doing so, Purdue protected its own profits at the expense of public health and safety.

84. The State of New York's settlement with Purdue specifically cited the company for failing to adequately address suspicious prescribing. Yet, on information and belief, Purdue continues to profit from the prescriptions of such prolific prescribers.

85. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse, diversion, and inappropriate prescribing; paid bonuses to sales representatives for detailing prescribers who were subsequently arrested or convicted for illegal prescribing; and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

86. As a part of their deceptive marketing scheme, Defendants identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including New York. For example, Defendants focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and therefore more likely to accept Defendants' misrepresentations.

87. Defendants also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. Defendants targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them, and the 2016 CDC guidelines conclude that there are special risks associated with the long-term use of opioids for elderly patients. (See Exhibit "F"). The same is true for veterans, who are more likely to use anti-anxiety drugs for post-traumatic stress disorder, which interact dangerously with opioids.

88. Defendants, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Defendants of this, and Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths - all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements based on the medical evidence that conclusively expose the known falsity of Defendants' misrepresentations, and Endo and Purdue have recently entered agreements prohibiting them from making some of the same misrepresentations described in this Complaint in New York.

89. Moreover, at all times relevant to this Complaint, Defendants took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful,

unfair, and fraudulent conduct. For example, Defendants disguised their own role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and paid consultant doctors. Defendants purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of Defendants' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain.

90. Defendants also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. Defendants exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with paid consultant doctors, Front Groups, and public relations companies that were not, and have not yet become, public. For example, painknowledge.org, which is run by the National Initiative on Pain Control ('NIPC"), did not disclose Endo's involvement. Other Defendants, such as Purdue and Janssen, ran similar websites that masked their own direct role.

91. Finally, Defendants manipulated their promotional materials and the scientific literature to make it appear as if these items were accurate, truthful, and supported by objective evidence when they were not. Defendants distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The lack of support for Defendants' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the State of New York.

92. Thus, Defendants successfully concealed from the medical community, patients, and health care payers facts sufficient to arouse suspicion of the claims that the

State now asserts. The State did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

93. Defendants' misrepresentations deceived doctors and patients about the risks and benefits of long-term opioid use. Studies also reveal that many doctors and patients are not aware of or do not understand these risks and benefits. Indeed, patients often report that they were not warned they might become addicted to opioids prescribed to them. As reported in January 2016, a 2015 survey of more than 1,000 opioid patients found that 4 out of 10 were not told opioids were potentially addictive. (Please see Hazelden Betty Ford Foundation, *Missed Questions, Missed Opportunities (Jan. 27, 2016,* attached hereto and incorporated by reference as Exhibit "I".)

94. Defendants' deceptive marketing scheme caused and continues to cause doctors in New York to prescribe opioids for chronic pain conditions such as back pain, headaches, arthritis, and fibromyalgia. Absent Defendants' deceptive marketing scheme, these doctors would not have prescribed as many opioids. Defendants' deceptive marketing scheme also caused and continues to cause patients to purchase and use opioids for their chronic pain believing they are safe and effective. Absent Defendants' deceptive marketing scheme, fewer patients would be using opioids long-term to treat chronic pain, and those patients using opioids would be using less of them.

95. Defendants' deceptive marketing has caused and continues to cause the prescribing and use of opioids to explode. Indeed, this dramatic increase in opioid prescriptions and use corresponds with the dramatic increase in Defendants' spending on

their deceptive marketing scheme. Defendants' spending on opioid marketing totaled approximately $91 million in 2000. By 2011, that spending had tripled to $288 million.

96. The escalating number of opioid prescriptions written by doctors who were deceived by Defendants' deceptive marketing scheme is the cause of a correspondingly dramatic increase in opioid addiction, overdose, and death throughout the U.S., and New York in particular. In August 2016, then-U.S. Surgeon General Vivek Murthy published an open letter to be sent to physicians nationwide, enlisting their help in combating this "urgent health crisis" and linking that crisis to deceptive marketing. He wrote that the push to aggressively treat pain, and the "devastating" results that followed, had "coincided with heavy marketing to doctors ... [m]any of [whom] were even taught - incorrectly - that opioids are not addictive when prescribed for legitimate pain. (Please see Exhibit "A".)

97. Scientific evidence demonstrates a strong correlation between opioid prescriptions and opioid abuse. In its 2016 report, the CDC explained that "[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses." Patients receiving prescription opioids for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical "to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity."

98. Contrary to Defendants' misrepresentations, most opioid addiction begins with legitimately *prescribed* opioids, and therefore could have been prevented had Defendants' representations to prescribers been truthful. In 2011, 71% of people who abused prescription opioids got them through friends or relatives, not from pill mills, drug dealers or the internet. Numerous doctors and substance abuse counselors note that many of their patients who

misuse or abuse opioids started with legitimate prescriptions, confirming the important role that doctors' prescribing habits have played in the opioid epidemic.

99. As the FDA observed in 2016, the opioid epidemic is getting worse, not better. Opioids are by far the most commonly prescribed class of substances in New York. And the connection and correlation between the increase in prescription opioid use and the overdose deaths occurring from prescription and nonprescription opioid and heroin use is clear. The National Institute on Drug Abuse ("NIDA"), a component of the National Institutes of Health ("NIH"), has identified several factors that have contributed to the nation's prescription opioid epidemic, including drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and aggressive marketing by the pharmaceutical companies. (Please see 2014 Congressional testimony presented by NIDA Director Nora Volkow, MD, attached hereto and incorporated herein by reference at Exhibit "J".)

100. Reported overdose death in New York in which heroin was a contributing cause reached a record high of 825 in 2014, the last year for which data are available from the CDC's National Center for Health Statistics ("NCHS"). This number represents a jump of 159 deaths, or 23.9%, over 2013; it is nearly twenty-five times the number recorded in New York ten years earlier. The number of overdose deaths in New York in which prescription opioids were a contributing cause also reached a new peak of 1,008 in 2014, up a fraction (0.9%) from 2013, and nearly quadruple the number of prescription opioid overdose fatalities recorded in 2005. (Please see *Prescription Opioid Abuse and Heroin Addiction in New York State*, report from the Office of the New York

State Comptroller, June 2016, attached hereto and incorporated herein by reference as Exhibit "K".)

101. One county in New York saw almost 2 dozen heroin-related deaths between January 29 and February 9 of this year - 2017, causing a backlog of pending overdose cases at the Erie County Medical Examiner's Office. Opiate-related deaths in the county for 2015 are expected to hit 264, possibly 300, when all of the toxicology tests are completed for the year. In 2014, there were 128 fatal overdoses. (Please see, *Deadly batch of heroin has killed 23 in Erie County since Jan. 29*, Lou Michel, Buffalo News, attached hereto and incorporated herein by reference as Exhibit "L".)

102. In 2010, New York opioid-related deaths totaled 962: deaths from natural opioids, such as hydrocodone and oxycodone – 526; deaths from synthetic opioids (except methadone), such a fentanyl and tramadol – 173; deaths from methadone – 263. In 2015, the last year for data are available, New York opioid-related deaths totaled 1619: deaths from natural opioids, such as hydrocodone and oxycodone – 705; deaths from synthetic opioids (except methadone), such a fentanyl and tramadol – 668; deaths from methadone – 246. (Please see The Henry J. Kaiser Family Foundation, Opioid Overdose Deaths by Type of Opioid, New York, 2010 and 2015, available at KFF.org.)

103. Defendants' deceptive marketing scheme has also had a significant detrimental impact on children and newborns in New York and across the nation. Reuters New Service identified 110 cases since 2010 of babies and toddlers whose mothers used opioids during pregnancy and who later died preventable deaths. Of those deaths, expectant mothers typically had been using heroin, synthetic painkillers that include such drugs as Percocet and OxyContin, or methadone, an opioid often prescribed as an alternative to heroin or the other

medications. (Please see *"Helpless and Hooked: The most vulnerable victims of America's opioid epidemic*, Duff Wilson and John Shiffman, Reuters, December 7, 2015, attached hereto and incorporated herein by reference as Exhibit "M".)

104. Further, the number of child abuse and neglect cases arising out of the opioid epidemic is buckling child welfare agencies across the state. New York's safety net for abused and neglected children is under stress — with caseworkers charged with keeping those youngsters safe often overwhelmed with more cases than they can handle, according to some of their advocates. Fueling rising caseloads in some counties, according to lawmakers and union officials, has been the epidemic of opiate addiction across upstate New York. "The opiate problem snowballed so quickly that nobody saw it coming," said Joe Musso, president of CSEA Local 884 for Clinton County's workers, including the county's Child Protective Services ("CPS") investigators. "When a mother or father becomes addicted, the entire family is impacted, and it's not a healthy environment for children to be in." (Please see *Child-protective workers warn system is swamped*, Joe Mahoney, The Daily Star, June 20, 2017, attached hereto and incorporated herein by reference as Exhibit "N".)

105. Defendants' creation, through false and deceptive advertising and other unlawful and unfair conduct, of a virtually limitless opioid market has significantly harmed communities throughout New York. Defendants' success in extending the market for opioids to new patients and chronic pain conditions has created an abundance of drugs available for non-medical and criminal use and fueled a new wave of addiction and injury. It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through doctors' prescriptions. (Please see *Prescription Opioid Abuse: Challenges and Opportunities*

*for Payers*, Nathaniel Katz, *et al*, American Journal of Managed Care, April 19, 2013, attached hereto and incorporated herein by reference at Exhibit "O".)

106. Law enforcement agencies have increasingly associated prescription drug abuse with violent and property crimes. Despite strict federal regulation of prescription drugs, local law enforcement agencies are faced with increasing diversion from legitimate sources for illicit purposes, including: doctor shopping, forged prescriptions, falsified pharmacy records, and employees who steal from their place of employment. The opioid epidemic has prompted a growing trend of crimes against pharmacies including robbery and burglary. In fact, a 2005 study by The Center on Addiction and Substance Abuse at Columbia University revealed that, by that time, 20.9% of pharmacies nationwide had stopped stocking certain medications such as OxyContin and Percocet, in order to protect themselves from robbery. This ongoing diversion of prescription narcotics creates a lucrative marketplace.

107. The costs and consequences of opioid addiction are staggering. Prescription opioid misuse, abuse and overdose have an enormous impact on the health and safety of individuals as well as communities at large, as the consequences of this epidemic reach far beyond the individual who is addicted. Some of the repercussions for individuals include job loss, loss of custody of children, physical and mental health problems, homelessness and incarceration. This results in instability in communities often already in economic crisis and contributes to increased demand on community services such as hospitals, courts, child services, treatment centers and law enforcement. (Please see Exhibit "K".)

108. Defendants knew and should have known about these harms that their deceptive marketing has caused. Defendants closely monitored their sales and the habits of

prescribing doctors. Their sales representatives, who visited doctors and attended CMEs, knew which doctors were receiving their messages and how they were responding. Defendants also had access to and watched carefully government and other data that tracked the explosive rise in opioid use, addiction, injury, and death. They knew - and, indeed, intended - that their misrepresentations would persuade doctors to prescribe and patients to use their opioids for chronic pain.

109. Defendants' actions are not permitted nor excused by the fact that their drug labels (with the exception of the Actiq/Fentora labels) may have allowed or did not exclude the use of opioids for chronic pain. FDA approval of opioids for certain uses did not give Defendants license to misrepresent the risks and benefits of opioids. Indeed, Defendants' misrepresentations were directly contrary to pronouncements by and guidance from the FDA based on the medical evidence and their own labels.

110. Nor is Defendants' causal role broken by the involvement of doctors. Defendants' marketing efforts were ubiquitous and highly persuasive. Their deceptive messages tainted virtually every source doctors could rely on for information and prevented them from making informed treatment decisions. Defendants also were able to harness and hijack what doctors wanted to believe - namely, that opioids represented a means of relieving their patients' suffering and of practicing medicine more compassionately.

111. Between 2006 and 2016, the Department of Medicaid spent nearly $175 million on Defendants' opioids. Many of these prescriptions were for chronic pain, and the State would not have paid for them had Defendants told the truth about the risks and benefits of their drugs.

112. Similarly, New York's Workers' Compensation paid for excessive opioid prescriptions due to Defendants' deceptive marketing practices. While the number of prescribed opioid prescriptions are slowly decreasing under the Workers Compensation program due to New York State efforts for reform, at $450.90 per-user-per-year, opioids are the costliest class off medications for occupational injuries. (Please see *Express Scripts: Workers'' Comp Prescription Drug Spend Increases 2.2% in* 2015, Claims Journal, April 7, 2016, attached hereto and incorporated herein by reference at Exhibit "P".)

113. Nationally, claims involving workers who take opioids are almost four times more likely to reach costs of over $100,000 than claims involving workers without opioids because opioid patients suffer greater side effects and are slower to return to work. (*The Effect of Opioid Use on Workers' Compensation Claim Cost in the State of Michigan*, Jeffrey A. White, MS, Journal of Occupational & Environmental Medicine, August 2012). Even adjusting for injury severity and self-reported pain score, receiving an opioid for more than seven days and receiving more than one opioid prescription increased the risk that a patient will be on work disability one year later. (Please see Gary M. Franklin, *et al., Early Opioid Prescription and Subsequent Disability Among Workers with Back Injuries: The Disability Risk Identification Study Cohort,* 33(2) *Spine* 199-204 (2008).) A prescription for opioids as the first treatment for a workplace injury doubled the average length of the claim. (Please see Dongchun Wang, *et al., Longer-Term Use of Opioids,* Workers Comp. Res. Inst. (Oct. 2012).)

114. While the use of opioids has taken an enormous toll on the State of New York and its residents, Defendants have realized blockbuster profits. In 2014 alone, opioids generated $11 billion in revenue for drug companies like Defendants. Indeed, financial

information indicates that each Defendant experienced a material increase in sales, revenue, and profits from the false and deceptive advertising and other unlawful and unfair conduct described above.

**AS AND FOR A SEPARATE AND DISTINCT FIRST CAUSE OF ACTION – COMMON LAW FRAUD, RELATOR/PLAINTIFF ALLEGES UPON INFORMATION AND BELIEF AS FOLLOWS:**

115. Relator/Plaintiff repeats, re-alleges and incorporates by reference each of the allegations set forth above as if fully set forth below.

116. The State realleges and incorporates by reference each of the allegations contained in the preceding paragraphs of this Complaint as though fully alleged herein.

117. As alleged herein, Defendants engaged in false representations and concealments of material fact regarding the use of opioids to treat chronic non-cancer pain.

118. Defendant Purdue made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to New York consumers that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;
- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements

concerning the indicators of possible opioid abuse;

- Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid paid consultant doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pam;

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-

cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Exclusively disseminating misleading statements in education materials to New York hospital doctors and staff while purportedly educating them on new pain standards;

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing; and

- Withholding from New York law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

119. Defendant Endo made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high- risk patients;

- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

- Disseminating misleading statements concealing the true risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid paid consultant doctors, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing needed financial support to pro-opioid pain organizations - including over $5 million to the organization responsible for many of the most egregious misrepresentations - that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that

deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing.

120. Defendant Janssen made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

- Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it

conducted, that opioids were not efficacious and concealing this information;

- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose- dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid paid consultant doctors, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing.

121. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- Providing significant financial support to pro-opioid paid consultant doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

- Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

- Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing and speakers' bureau events.

122. Defendant Actavis made and/or disseminated deceptive statements, including, but not limited to, the following:

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing;

- Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic noncancer pain and that opioids improve quality of life;

- Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

- Developing and disseminating scientific sh1dies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contrary data.

123. These false representations and concealments were reasonably calculated to deceive the State and the physicians who submitted prescriptions for payment to the State, were made with the intent to deceive, and did in fact deceive the State and the physicians who submitted prescriptions for payment to the State, which paid for prescription opioids for chronic pain.

124. But for these false representations and concealments of material fact, the State and its agencies would not have incurred millions of dollars in overpayments.

125. The State and the physicians who submitted opioid prescriptions for payment to the State reasonably relied on these false representations and concealments of material fact.

126. As a direct and proximate cause of Defendants' fraudulent conduct, the Relator/Plaintiff and State of New York has been injured.

**AS AND FOR A SECOND SEPARATE AND DISTINCT CAUSE OF ACTION – VIOLATION OF FALSE CLAIMS ACT (FCA § 3729(a)(1)(A)), RELATOR/PLAINTIFF ALLEGES UPON INFORMATION AND BELIEF AS FOLLOWS:**

127. Relator/Plaintiff repeats, re-alleges and incorporates herein by reference all allegations set forth above as if fully set forth below.

128. By the practices described, and upon reasonable belief and knowledge, the Defendants presented the United States Government and the State of New York with false or artificially inflated claims, or presented to a contractor, guarantee or other recipient to be used on those governments' behalf or to advance a government program or interest.

129. As more particularly set forth in the foregoing paragraphs, by virtue of the acts alleged herein, upon information and belief, the Defendants have knowingly presented or caused to be presented to officers or employees of the United States Government and governments of individual states, false or fraudulent claims for payment or approval in violation of 31 U.S.C. Sec. 3729 (a)(1).

130. Defendants did so with actual knowledge of the falsity of each claim, with reckless disregard for the truth and falsity of each claim, or with deliberate indifference to the truth or falsity of each claim.

131. Upon information and belief, Defendants' claims were paid by the United States Government and governments of individual states, including, but not limited to the State of New York.

132. As a direct and proximate cause of Defendants' violations of the False Claims Act, the Relator/Plaintiff and State of New York has been injured.

**AS AND FOR A THIRD SEPARATE AND DISTINCT CAUSE OF ACTION – FALSE STATEMENTS (FCA § 3729(a)(1)(B)), RELATOR/PLAINTIFF ALLEGES UPON INFORMATION AND BELIEF AS FOLLOWS:**

133. Relator/Plaintiff repeats, re-alleges and incorporates herein by reference all allegations set forth above as if fully set forth below.

134. As more particularly set forth in the foregoing paragraphs, and upon reasonable belief and knowledge, Defendants knowingly made, used, or caused to be made or used, false records and statements material to have false or fraudulent claims paid or approved by the United States Government and/or the Individual States' governments, including but not limited to the State of New York, in violation of 3729(a)(1)(B). Upon information and belief, such false

records or statements included but were not limited to prescriptions, billings, medical statements, deliveries, surveys, invoices, or other documentation requesting reimbursement for unnecessary and inflated costs.

135. As a direct and proximate cause of Defendants' false statements, in violation of the False Claims Act, the Relator/Plaintiff and State of New York has been injured.

**AS AND FOR A FOURTH SEPARATE AND DISTINCT CAUSE OF ACTION – CONSPIRACY TO COMMIT VIOLATIONS OF THE FALSE CLAIMS ACT (FCA § 3729(a)(1)(C)) RELATOR/PLAINTIFF ALLEGES UPON INFORMATION AND BELIEF AS FOLLOWS:**

136. Relator/Plaintiff repeats, re-alleges and incorporates herein by reference all allegations set forth above as if fully set forth below.

137. As more particularly set forth in the foregoing paragraphs, and upon reasonable belief and knowledge, the Defendants conspired to commit violations of the False Claims Act, 31 U.S.C. § 3729, Subsections (A), (B), (D), (E), (F) and (G).

138. As a direct and proximate cause of Defendants' conspiracy to commit violations of the False Claims Act, the Relator/Plaintiff and State of New York has been injured.

**AS AND FOR A FIFTH SEPARATE AND DISTINCT CAUSE OF ACTION – <u>REVERSE FALSE CLAIMS (FCA § 3729(a)(7) and 3729 (a)(1)(G))</u> RELATOR/PLAINTIFF ALLEGES UPON INFORMATION AND BELIEF AS FOLLOWS:**

139. Relator/Plaintiff repeats, re-alleges and incorporates herein by reference all allegations set forth above as if fully set forth below.

140. As more particularly set forth in the foregoing paragraphs, by virtue of the alleged acts, and upon reasonable belief and knowledge, Defendants knowingly made, used, or caused to be made or used, false records and statements material to an obligation to pay or

transmit money or property to the United States or other government, or knowingly concealed, improperly avoided or decreased an obligation to pay or transmit money or property to such government.

141. As a direct and proximate cause of Defendants' reverse false claims, in violation of the False Claims Act, the Relator/Plaintiff and State of New York has been injured.

**AS AND FOR A SIXTH SEPARATE AND DISTINCT CAUSE OF ACTION – NEW YORK FALSE CLAIMS ACT (N.Y. CLS ST. FIN. SEC. 186 *et seq.*) RELATOR/PLAINTIFF ALLEGES UPON INFORMATION AND BELIEF AS FOLLOWS:**

142. Relator/Plaintiff repeats, re-alleges and incorporates herein by reference all allegations set forth above as if fully set forth below.

143. This is a claim for treble damages and civil penalties under the New York False Claims Act., N.Y. CLS St. Fin.Sec.186 *et seq*.

144. By virtue of the schemes and submissions described above, and upon reasonable belief and knowledge, Defendants knowingly caused to be presented to the New York Medicaid Program false claims for the improper payment or approval of prescriptions, and Defendants used false or fraudulent records to accomplish this purpose.

145. The New York Medicaid Program, unaware of the falsity or fraudulent nature of the claims caused by the Defendants, paid for claims that otherwise would not have been allowed.

146. By reason of these payments, the New York Medicaid Program has been damaged, and continues to be damaged in a substantial amount.

147. As a direct and proximate cause of Defendants' violations of New York's False Claims Act, the Relator/Plaintiff and State of New York has been injured.

**AS AND FOR A SEVENTH SEPARATE AND DISTINCT CAUSE OF ACTION – DECEPTIVE AND UNLAWFUL ACTS AND PRACTICES (N.Y. General Business Law § 349, RELATOR/PLAINTIFF ALLEGES UPON INFORMATION AND BELIEF AS FOLLOWS:**

148. Relator/Plaintiff repeats, re-alleges and incorporates herein by reference all allegations set forth above as if fully set forth below.

149. By virtue of the schemes and submissions described above, and upon reasonable belief and knowledge, Defendants disseminated false information, withheld information that would be necessary for the consuming public to make a fully informed decision about the Defendants' products and/or services, and misled the State of New York, and consuming public at large, regarding the true nature of the opioid drugs the Defendants marketed, sold, and distributed within the State of New York.

150. By virtue of the schemes and submissions described above, and upon reasonable belief and knowledge, Defendants' representations, claims, and/or assertions of fact, orally and/or in writing regarding the true nature of their opioid drugs caused the State of New York, and the consuming public at large, to believe such statements were true, and that the State of New York, and the consuming public at large, reasonably relied upon Defendants' statements. \

151. Defendant PURDUE made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to New York consumers that contained deceptive statements;

- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

- Disseminating misleading statements concealing the true

risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

- Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid paid consultant doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic

non-cancer pain;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Exclusively disseminating misleading statements in education materials to New York hospital doctors and staff while purportedly educating them on new pain standards;
- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing; and

- Withholding from New York law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they knew would reach these same prescribers.

152. Defendant ENDO made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the

treatment of chronic non-cancer pain;

- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high-risk patients;

- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;

- Disseminating misleading statements concealing the hue risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;

- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid Paid consultant doctors, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing needed financial support to pro-opioid pain organizations - including over $5 million to the organization responsible for many of the most egregious misrepresentations- that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that

deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing.

153. Defendant JANNSEN made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

- Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid paid consultant doctors, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while concealing contrary data;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer

pain, including known rates of abuse and addiction and the lack of validation for long-tern1 efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing.

154. Defendant CEPHALON made and/or disseminated untrue, false and deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- Providing significant financial support to pro-opioid paid consultant doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of

Cephalon's rapid-onset opioids;

- Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

- Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing and speakers' bureau events, when such uses are unapproved and unsafe; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing and speakers' bureau events.

155. Defendant ACTAVIS made and/or disseminated deceptive statements, including, but not limited to, the following:

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing;

- Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

- Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contraly data.

- These deceptive representations and concealments were reasonably calculated to deceive the State of New York and the consuming public at large, were made with the intent to deceive the State of New York and the consuming public at large. and did in fact deceive the State and New York

consumers, who paid for prescription opioids for chronic pain.

156. As described more specifically above, Defendants' representations and concealments constitute a course of conduct which continues to this day.

157. But for these deceptive representations and concealments of material fact, the State of New York and New York consumers would not have incurred millions of dollars in overpayments.

158. As a direct and proximate cause of Defendants' deceptive conduct, the State of New York and New York consumers have been injured in an amount to be determined at trial.

**AS AND FOR AN EIGHTH SEPARATE AND DISTINCT CAUSE OF ACTION–FALSE AND UNLAWFUL ADVERTISING (N.Y. General Business Law § 350 RELATOR/PLAINTIFF ALLEGES UPON INFORMATION AND BELIEF AS FOLLOWS:**

159. Relator/Plaintiff repeats, re-alleges and incorporates herein by reference all allegations set forth above as if fully set forth below.

160. By virtue of the schemes and submissions described above, and upon reasonable belief and knowledge, Defendants falsely advertised their opioid drugs, thereby misleading the State of New York and the consuming public at large regarding a material aspect of their opioid drugs.

161. By virtue of the schemes and submissions described above, and upon reasonable belief and knowledge Defendants' false and misleading advertising regarding the true nature of their opioid drugs caused the State of New York, and the consuming public at large, to believe such statements were true, and that the State of New York, and the consuming public at large, reasonably relied upon Defendants' statements.

162. Defendant Purdue falsely and misleadingly advertisements include, but are not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials distributed to New York consumers that contained deceptive statements;

- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;

- Disseminating misleading statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through Purdue's own unbranded publications and on internet sites Purdue operated that were marketed to and accessible by consumers;

- Distributing brochures to doctors, patients, and law enforcement officials that included deceptive statements concerning the indicators of possible opioid abuse;

- Sponsoring, directly distributing, and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid paid consultant doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain; Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented· the risks of opioid addiction;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that misleadingly concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Exclusively disseminating misleading statements in education materials to New York hospital doctors and staff while purportedly educating them on new pain standards;

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing; and

- Withholding from New York law enforcement the names of prescribers Purdue believed to be facilitating the diversion of its products, while simultaneously marketing opioids to these doctors by disseminating patient and prescriber education materials and advertisements and CMEs they

knew would reach these same prescribers.

163. Defendant Endo made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;
- Creating and disseminating advertisements that contained deceptive statements concerning the ability of opioids to improve function long-term and concerning the evidence supporting the efficacy of opioids long-term for the treatment of chronic non-cancer pain;
- Creating and disseminating paid advertisement supplements in academic journals promoting chronic opioid therapy as safe and effective for long term use for high-risk patients;
- Creating and disseminating advertisements that falsely and inaccurately conveyed the impression that Endo's opioids would provide a reduction in oral, intranasal, or intravenous abuse;
- Disseminating misleading statements concealing the hue risk of addiction and promoting the misleading concept of pseudoaddiction through Endo's own unbranded publications and on internet sites Endo sponsored or operated;
- Endorsing, directly distributing, and assisting in the distribution of publications that presented an unbalanced treatment of the long-term and dose-dependent risks of opioids versus NSAIDs;
- Providing significant financial support to pro-opioid Paid consultant doctors, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;
- Providing needed financial support to pro-opioid pain organizations - including over $5 million to the organization responsible for many of the most egregious

misrepresentations- that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contra1y data;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-term efficacy; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing.

164. Defendant Janssen made and/or disseminated deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Directly disseminating deceptive statements through internet sites over which Janssen exercised final editorial control and approval stating that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life, while concealing contrary data;

- Disseminating deceptive statements concealing the true risk of addiction and promoting the deceptive concept of pseudoaddiction through internet sites over which Janssen exercised final editorial control and approval;

- Promoting opioids for the treatment of conditions for which Janssen knew, due to the scientific studies it conducted, that opioids were not efficacious and concealing this information;

- Sponsoring, directly distributing, and assisting in the dissemination of patient education publications over which Janssen exercised final editorial control and approval, which presented an unbalanced treatment of the long-term and dose dependent risks of opioids versus NSAIDs;

- Providing significant financial support to pro-opioid paid consultant doctors, who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Providing necessary financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Targeting the elderly by assisting in the distribution of guidelines that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain and misrepresented the risks of opioid addiction in this population;

- Targeting the elderly by sponsoring, directly distributing, and assisting in the dissemination of patient education publications targeting this population that contained deceptive statements about the risks of addiction and the adverse effects of opioids, and made false statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and improve quality of life, while

concealing contrary data;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Directly distributing and assisting in the dissemination of literature written by pro-opioid paid consultant doctors that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain, including the concept of pseudoaddiction;

- Creating, endorsing, and supporting the distribution of patient and prescriber education materials that misrepresented the data regarding the safety and efficacy of opioids for the long-term treatment of chronic non-cancer pain, including known rates of abuse and addiction and the lack of validation for long-tern1 efficacy;

- Targeting veterans by sponsoring and disseminating patient education marketing materials that contained deceptive statements concerning the use of opioids to treat chronic non-cancer pain; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing.

165. Defendant Cephalon made and/or disseminated untrue, false and deceptive statements, including, but not limited to, the following:

- Creating, sponsoring, and assisting in the distribution of patient education materials that contained deceptive statements;

- Sponsoring and assisting in the distribution of publications that promoted the deceptive concept of pseudoaddiction, even for high-risk patients;

- Providing significant financial support to pro-opioid paid consultant doctors who made deceptive statements concerning the use of opioids to treat chronic non-cancer pain and breakthrough chronic non-cancer pain;

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain in conjunction with Cephalon's potent rapid-onset opioids;

- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of opioids to treat chronic non-cancer pain;

- Endorsing and assisting in the distribution of CMEs containing deceptive statements concerning the use of Cephalon's rapid-onset opioids;

- Directing its marketing of Cephalon's rapid-onset opioids to a wide range of doctors, including general practitioners, neurologists, sports medicine specialists, and workers' compensation programs, serving chronic pain patients;

- Making deceptive statements concerning the use of Cephalon's opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing and speakers bureau events, when such uses are unapproved and unsafe; and

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing and speakers bureau events.

166. Defendant Actavis made and/or disseminated deceptive statements, including, but not limited to, the following:

- Making deceptive statements concerning the use of opioids to treat chronic non-cancer pain to New York prescribers through in-person detailing;

- Creating and disseminating advertisements that contained deceptive statements that opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life;

- Creating and disseminating advertisements that concealed the risk of addiction in the long-term treatment of chronic, non-cancer pain; and

- Developing and disseminating scientific studies that deceptively concluded opioids are safe and effective for the long-term treatment of chronic non-cancer pain and that opioids improve quality of life while concealing contraly data.

167. These deceptive, false and misleading advertisements were reasonably calculated to deceive the State of New York and the consuming public at large, were made with the intent to deceive the State of New York and the consuming public at large, and did in fact deceive the State and New York consumers, who paid for prescription opioids for chronic pain.

168. As described more specifically above, Defendants' false, misleading and deceptive advertising constitute a course of conduct which continues to this day.

169. But for these false, misleading and deceptive advertising, the State of New York and New York consumers would not have incurred millions of dollars in overpayments.

170. As a direct and proximate cause of Defendants' deceptive and false advertising, the Relator/Plaintiff, State of New York and New York consumers have been injured in an amount to be determined at trial.

**AS AND FOR A NINTH SEPARATE AND DISTINCT CAUSE OF ACTION – VIOLATIONS OF THE FEDERAL RACKETEER-INFLUENCED AND CORRUPT ORGANIZATION ACT ("RICO") (18 USC§1962), RELATOR/ PLAINTIFF ALLEGES UPON INFORMATION AND BELIEF AS FOLLOWS:**

171. Relator/Plaintiff repeats, re-alleges and incorporates herein by reference all allegations set forth above as if fully set forth below.

172. By virtue of the schemes and submissions described above, and upon reasonable belief and knowledge this claim is brought by the State of New York against Defendants for all

damages and equitable relief allowed under the Federal Racketeer-Influences and Corrupt Organization Act ("the RICO Act") (18 USC § 1962).

173. The Defendants are "persons" within the meaning the RICO Act, who conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of 18 USC §1962, and whose activities affect interstate commerce.

174. The State is a "person," within the meaning the RICO Act, who was injured in its business or property as a result of Defendants' wrongful conduct. Specifically, the State of New York, including the Departments of Medicaid and Workers' Compensation, paid for more prescriptions for opioids for chronic pain than it would have paid had Defendants, directly or through paid consultant doctors or Front Groups, told the truth about the risks and benefits about their drugs.

**A. The Opioids Marketing Enterprise**

175. Defendants formed an association-in-fact enterprise - sometimes referenced to in this Complaint as the Opioids Marketing Enterprise. The Opioids Marketing Enterprise consists of (a) Defendants, including their employees and agents; (b) the Front Groups, including their employees and agents; and (c) their paid consultant doctors.

176. The Opioids Marketing Enterprise is an ongoing and continuing business organization that created and maintained systematic links for a common purpose: to ensure the prescription of opioids for chronic pain.

177. To accomplish this purpose, the Opioids Marketing Enterprise periodically and systematically misrepresented - either affirmatively or through half-truths and omissions - to the general public, the State of New York and New York consumers, the risks and benefits of using opioids for chronic pain. The Opioids Marketing Enterprise concealed from the public, the State

of New York, and New York consumers, the serious risks and lack of corresponding benefits of using opioids for chronic pain. By making those representations, the Opioids Marketing Enterprise ensured that a larger number of opioid prescriptions would be written and filled for chronic pain. This translated into higher sales (and therefore profits) for Defendants.

178. The persons engaged in the Opioids Marketing Enterprise are systematically linked through contractual relationships, financial ties, and continuing coordination of activities, as spearheaded by Defendants. There is regular communication between Defendants, Front Groups and paid consultant doctors, in which information is shared. Typically, this communication occurred, and continues to occur, through the use of the wires and the mail in which Defendants, Front Groups and paid consultant doctors share information regarding overcoming objections to the use of opioids for chronic pain. Defendants, the Front Groups and paid consultant doctors functioned as a continuing unit for the purposes of implementing the Opioids Marketing Scheme and, when issues arise during the scheme, each agreed to take actions to hide the scheme and continue its existence.

179. At all relevant times, Front Groups were aware of Defendants' conduct, were a knowing and willing participant in that conduct, and reaped benefits from that conduct. Each Front Groups also knew, but did not disclose, that the other Front Groups were engaged in the same scheme, to the detriment of the State and New York consumers. But for the Opioids Marketing Enterprise's unlawful fraud, Front Groups would have had the incentive to disclose the deceit by Defendants to their members and constituents. By failing to disclose this information, Front Groups perpetuated the Opioids Marketing Enterprise's scheme, and reaped substantial benefits.

180. At all relevant times, paid consultant doctors were aware of Defendants' conduct,

were knowing and willing participants in that conduct, and reaped profits from that conduct. Defendants selected paid consultant doctors solely because they favored the aggressive treatment of chronic pain with opioids. Defendants' support helped these doctors become respected industry experts. And, as they rose to prominence, these doctors touted the benefits of opioids to treat chronic pain, repaying Defendants by advancing their marketing goals. The paid consultant doctors also knew, but did not disclose, that the other paid consultant doctors and Front Groups were engaged in the same scheme, to the detriment of consumers and the State of New York. But for the Opioids Marketing Enterprise's unlawful fraud, paid consultant doctors would have been incentivized to disclose the deceit, and to protect their patients and the patients of other physicians. By failing to disclose this information, paid consultant doctors perpetuated the Opioids Marketing Enterprise's scheme, and reaped substantial benefits.

181. Furthermore, as public scrutiny and media coverage have focused on how opioids have ravaged communities in the State of New York and throughout the United States, the Front Groups and paid consultant doctors did not challenge Defendants' misrepresentations, seek to correct their previous misrepresentations, terminate their role in the Opioids Marketing Enterprise, nor disclose publicly that the risks of using opioids for chronic pain outweighed their benefits.

182. The Front Groups and paid consultant doctors participated in the conduct of the Opioids Marketing Enterprise, sharing the common purpose of marketing opioids for chronic pain and, through a pattern of racketeering activity, which includes multiple instances of mail fraud, and multiple instances of wire fraud, they knowingly made material misstatements or omissions to New York physicians, consumers, the State of New York and the general public in furtherance of the fraudulent scheme, including that:

- it was rare, or there was a low risk, that Defendants' opioids could lead to addiction;
- Providing needed financial support to pro-opioid pain organizations that made deceptive statements, including in patient education materials, concerning the use of opioids to treat chronic non-cancer pain;
- the signs of addiction were actually signs of undertreated pain that should be treated by more opioids;
- opioid dependence could be easily addressed by tapering and that opioid withdrawal is not difficult;
- doctors could increase opioid dosages indefinitely without added risk;
- long-term opioid use improved patients' function and quality of life;
- Purdue's OxyContin provided 12 hours of continuous pain relief; and
- the extent to which the Opioids Marketing Scheme caused the State of New York and New York consumers to pay for excessive opioid prescriptions, and to incur costs associated with abating the opioid epidemic caused by the Enterprise.

183. Defendants alone could not have accomplished the purpose of the Opioids Marketing Enterprise without the assistance of the Front Groups and paid consultant doctors, who were perceived as "neutral" and more "scientific" than Defendants themselves. Without these misrepresentations, the Opioids Marketing Enterprise could not have achieved its common purpose.

184. The impacts of the Opioids Marketing Enterprise's scheme are still in place- i.e., the opioids continue to be prescribed and used for chronic pain throughout the State of New York, and the epidemic continues to consume the resources of New York's health care and law enforcement systems.

185. The foregoing evidences that Defendants, the Front Groups and the paid consultant doctors were each willing participants in the Opioids Marketing Enterprise, had a common purpose and interest in the object of the scheme, and functioned within a structure designed to effectuate the Enterprise's purpose.

**B. Conduct of the Opioids Marketing Enterprise**

186. During time period described in this Complaint, from approximately 2006 to the present, Defendants exerted control over the Opioids Marketing Enterprise and participated in the operation or management of the affairs of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

- Defendants created a body of deceptive and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was thus more likely to be relied upon by physicians, patients, and payors;

- Defendants selected, cultivated, promoted and paid the Paid consultant doctors based solely on their willingness to communicate and distribute Defendants' messages about the use of opioids for chronic pain;

- Defendants provided substantial opportunities for Paid consultant doctors to participate in research studies on topics Defendants suggested or chose, with the predictable effect of ensuring that many favorable studies appeared in the academic literature;

- Defendants paid consultant doctors to serve as consultants or on their advisory boards and to give talks or present CMEs, typically over meals or at conferences;

- Defendants disseminated many of their false, misleading, imbalanced, and unsupported statements through unbranded materials that appeared to be independent publications from Front Groups;

- Defendants sponsored CME programs put on by Front

Groups that focused exclusively on the use of opioids for chronic pain;

- Defendants developed and disseminated pro-opioid treatment guidelines;
- Defendants encouraged Front Groups to disseminate their pro-opioid messages to groups targeted by Defendants, such as veterans and the elderly, and then funded that distribution;
- Defendants concealed their relationship to and control of Front Groups and paid consultant doctors from the State and the public at large; and
- Defendants intended that Front Groups and paid consultant doctors would distribute through the U.S. mail and interstate wire facilities, promotional and other materials that claimed opioids could be safely used for chronic pain.

187. The scheme had a hierarchical decision-making structure that was headed by Defendants. Defendants controlled representations made about their drugs, and doled out funds to PBMs and payments to paid consultant doctors to ensure the representations made were consistent with Defendants' messaging nationwide and throughout the State of New York. Front Groups were dependent on Defendants for their financial structure, and paid consultant doctors were professionally dependent on Defendants for the development and promotion of their careers.

- Defendants intended that Front Groups and paid consultant doctors would distribute through the U.S. mail and interstate wire facilities, promotional and other materials;
- The Front Groups promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages themselves;
- The Front Groups distribute through the U.S. Mail and interstate wire facilities promotional and other materials which claimed that opioids could be safely used for chronic pain, and the benefits of using opioids for chronic pain

outweighed the risks; and

- The Front Groups concealed their connections to Defendants.

188. The paid consultant doctors also participated in the conduct of the affairs of the Opioids Marketing Enterprise, directly or indirectly, in the following ways:

- The paid consultant doctors promised to, and did, make representations regarding Defendants' opioids that were consistent with Defendants' messages themselves;

- The paid consultant doctors distributed through the U.S. Mail and interstate wire facilities promotional and other materials which claimed that opioids could be safely used for chronic pain, and the benefits of using opioids for chronic pain outweighed the risks; and

- The paid consultant doctors concealed their connections to and sponsorship by Defendants.

189. The scheme devised and implemented by Defendants, as well as other members of the Opioids Marketing Enterprise, amounted to a common course of conduct intended to encourage the prescribing and use of opioids for chronic pain and thereby secure payment for prescriptions of Defendants' opioids by New York patients and the State of New York, including the Departments of Medicaid and Workers' Compensation. The scheme was a continuing course of conduct, and many aspects of it continue through to the present.

**C. Pattern of Racketeering Activity**

190. Defendants conducted and participated in the conduct of the affairs of the Opioids Marketing Enterprise through a pattern of racketeering activity as defined in 18 USC §1962. The pattern of racketeering activity by the Opioids Marketing Enterprise likely involved thousands of separate instances of use of the U.S. Mail or interstate wire facilities in furtherance of the unlawful Opioids Marketing Enterprise. Each of these fraudulent mailings and interstate wire

transmissions constitutes racketeering activity and collectively, these violations constitute a pattern of racketeering activity, through which Defendants, the Front Groups and the Paid consultant doctors defrauded and intended to defraud New York consumers, the State of New York, and other intended victims.

191. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including New York consumers and the State of New York. Defendants, the Front Groups and the paid consultant doctors calculated and intentionally crafted the opioids marketing scheme to ensure their own profits remained high, without regard to the effect such behavior had on New York consumers and the State of New York. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and scientific evidence regarding Defendants' products.

192. By intentionally misrepresenting the risks and benefits of using opioids for chronic pain, and then subsequently failing to disclose such practices to New York consumers or the State, Defendants, the Front Groups and the paid consultant doctors engaged in a fraudulent and unlawful course of conduct constituting a pattern of racketeering activity.

193. Defendants', the Front Groups' and the paid consultant doctors' racketeering activities amounted to a common course of conduct, with a similar pattern and purpose, intended to deceive the State of New York and New York consumers. Each separate use of the U.S. Mail and/or interstate wire facilities employed by Defendants was related, had similar intended purposes, involved similar participants and methods of execution, and had the same results affecting the same victims, including the State of New York and New York consumers.

Defendants have engaged in the pattern of racketeering activity for the purpose of conducting the ongoing business affairs of its Opioids Marketing Enterprise.

194. The pattern of racketeering activity alleged herein and the Opioids Marketing Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the Opioids Marketing Enterprise.

195. The pattern of racketeering activity alleged herein is continuing as of the date of this complaint, and, upon information and belief, will continue into the future unless enjoined by this Court.

196. Many of the precise dates of the Opioids Marketing Enterprise's uses of the U.S. Mail and interstate wire facilities (and corresponding predicate acts of mail and wire fraud) have been hidden and cannot be alleged without access to Defendants', the Front Groups' and the paid consultant doctors' books and records. Indeed, an essential part of the successful operation of the Opioids Marketing Enterprise alleged herein depended upon secrecy. However, the State of New York can generally describe the occasions on which the predicate acts of mail fraud and wire fraud occurred, and how those acts were in furtherance of the scheme, and do so below.

197. Defendants' use of the U.S. Mail and interstate wire facilities to perpetrate the opioids marketing scheme involved thousands of communications, including, *inter alia*:

- Marketing materials about Defendants' opioids, and their risks and benefits, which Defendants sent to health care providers located across the country and the State;
- Written representations and telephone calls between Defendants and Front Groups regarding representations about Defendants' opioids, or the use of opioids for chronic pain generally;
- Written representations and telephone calls between Defendants and paid consultant doctors regarding Defendants' opioids, or the use of opioids for chronic pain

generally;

- Hundreds of e-mails between Defendants and the Front Groups agreeing to or effectuating the implementation of the opioids marketing scheme;

- Hundreds of e-mails between Defendants and paid consultant doctors agreeing to or effectuating the implementation of the opioids marketing scheme;

- Hundreds of communications between the Front Groups and publications, groups drafting treatment guidelines and the media effectuating the implementation of the opioids marketing scheme;

- Hundreds of communications between the paid consultant doctors and publications, groups drafting treatment guidelines and the media effectuating the implementation of the opioids marketing scheme;

- Written and oral communications directed to State agencies and private insurers throughout the State that fraudulently misrepresented the risks of benefits of using opioids for chronic pain; and

- Receipts of increased profits sent through the U.S. Mail and interstate wire facilities - the wrongful proceeds of the scheme.

198. In addition to the above-referenced predicate acts, it was foreseeable to Defendants that the Front Groups and the paid consultant doctors would distribute publications through the U.S. Mail and by interstate wire facilities, and, in those publications, claim that the benefits of using opioids for chronic pain outweighed the risks of doing so.

**D. Damages Caused by Defendants' Fraud**

199. Defendants' violations of law and their pattern of racketeering activity have directly and proximately caused the State of New York, and specifically the Departments of Medicaid and Workers' Compensation, as well as consumers within the State of New York, to be

injured in their business or property because they have paid for opioid prescriptions for chronic pain for which they would not otherwise have paid.

200. The State of New York's injuries, and those of New York consumers, were proximately caused by Defendants' racketeering activity. But for the misstatements made by Defendants, the Front Groups and the paid consultant doctors and the scheme employed by the Opioids Marketing Enterprise, the State of New York and New York consumers would not have paid for opioid prescriptions for chronic pain.

201. The State of New York's injuries were directly caused by Defendants' racketeering activity. Although the misstatements made by the Front Groups and the paid consultant doctors in furtherance of the Opioids Marketing Enterprise were directed primarily to health care providers, those providers did not have to make payments for opioids prescribed for chronic pain. Therefore, New York health care providers did not suffer the same injuries alleged in this Complaint.

202. The Relator/Plaintiff, and the State of New York and its citizens were most directly harmed by the fraud, and there is no other Plaintiff or class of plaintiffs better situated to seek a remedy for the economic harms to consumers from Defendants' scheme.

203. By virtue of these violations 18 USC §1962, Defendants are liable to the State of New York for all damages allowed under the law, the damages Relator/Plaintiff has sustained, plus the cost of this suit, including reasonable attorneys' fees.

**AS AND FOR A TENTH SEPARATE AND DISTINCT CAUSE OF ACTION – VIOLATIONS OF NEW YORK ORGANIZED CRIME CONTROL ACT OF 1986 (NY Penal Code Article 460, et seq.), RELATOR/PLAINTIFF ALLEGES UPON INFORMATION AND BELIEF AS FOLLOWS:**

204. Relator/Plaintiff repeats, re-alleges and incorporates herein by reference all

allegations set forth above as if fully set forth below.

205. By virtue of the schemes and submissions described above, and upon reasonable belief and knowledge, this claim is brought by the State of New York against Defendants for all damages and equitable relief allowed under the New York Organized Crime Control Act of 1986 (NY Penal Code Article 460, et seq.).

206. The Defendants are "persons" within the meaning the New York Organized Crime Control Act, who conducted the affairs of an enterprise through a pattern of racketeering activity, in violation of NY Penal Code Article 460, et seq., and whose activities affect interstate commerce.

207. The State is a "person," within the meaning the New York Organized Crime Control Act, who was injured in its business or property as a result of Defendants' wrongful conduct. Specifically, the State of New York, including the Departments of Medicaid and Workers' Compensation, paid for more prescriptions for opioids for chronic pain than it would have paid had Defendants, directly or through paid consultant doctors or Front Groups, told the truth about the risks and benefits about their drugs.

208. The Relator/Plaintiff, and the State of New York and its citizens were most directly harmed by the Defendants' violations of NY Penal Code Article 460, et seq, and there is no other Plaintiff or class of plaintiffs better situated to seek a remedy for the economic harms to consumers from Defendants' fraudulent scheme.

209. By virtue of these violations NY Penal Code Article 460, et seq, Defendants are liable to the Relator/Plaintiff and the State of New York for all damages allowed under the law, the damages Relator/Plaintiff has sustained, plus the cost of this suit, including reasonable attorneys' fees.

**AS AND FOR AN ELEVENTH SEPARATE AND DISTINCT CAUSE OF ACTION – VIOLATIONS OF THE ANTI-KICKBACK ACT (18 U.S.C. 874 ET SEQ.), RELATOR/PLAINTIFF ALLEGES UPON INFORMATION AND BELIEF AS FOLLOWS:**

210. Relator/Plaintiff repeats, re-alleges and incorporates herein by reference all allegations set forth above as if fully set forth below.

211. By virtue of the allegations set forth above, and upon information and belief, the Defendants herein, and each, any or all of said Defendants, violated the Anti-Kickback Act, 18 U.S.C. 874 et seq., in that said Defendants paid the Front Groups, paid consultant doctors and other physicians, and other intermediaries kickbacks and other payments if said Front Groups, paid consultant doctors and other physicians, and other intermediaries would refer patient to or prescribe to patients the Defendants' opiate medications. Such paybacks and other payments were all part of the scheme that the aforesaid Defendants devised and orchestrated so as to defraud the public in general and otherwise colluded to instigate the very serious epidemic of opiate use in the United States today. The said violations of the Anti-Kickback Act led to an increase and exacerbation of the ongoing epidemic of opiates and heroine that now plagues the United States.

212. By virtue of these violations of the Anti-Kickback Act, the Defendants are liable to the Relator/Plaintiff and the State of New York for all damages allowed under the law, the damages Relator/Plaintiff has sustained, plus costs of this suit, including reasonable attorneys' fees.

**WHEREFORE**, for each claim, the *Qui Tam* Relator/Plaintiff request on behalf of themselves and the State of New York, the following relief from the Defendants:

A. That Defendants cease and desist from violating the False Claims Act, 31 USC § 3729;

B. That Relator/Plaintiff be awarded all specified damages and civil penalties of the False Claims Act for each violation of the statute;

C. That Relator/Plaintiff be awarded three times the amount of damages that the State of New York has sustained because of the acts of Defendants;

D. That Relator/Plaintiff be awarded the maximum "relator's share" allowed pursuant to 31 USC § 3729;

E. That Relator/Plaintiff be awarded for collecting the civil penalties and damages;

F. That Relator/Plaintiff be awarded all her costs, including reasonable attorneys' fees and costs;

G. That Relator/Plaintiff be awarded interest;

H. All compensatory and punitive damages with respect to the claims set forth in an amount to be determined by a jury; and

I. Such further relief as the Court deems just.

**JURY REQUEST**

*Qui Tam* Relator/Plaintiff request a jury for all issues that may be tried by a jury.

**Dated:** July 6, 2017

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